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The National Response Plan: A New Framework for Homeland Security, Public Health, and Bioterrorism Response

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The National Response Plan: A New Framework for Homeland Security, Public Health, and Bioterrorism Response

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ABSTRACT: This Article provides a detailed overview of the new National Response Plan (NRP) with a focus on its applicability to bioterrorism and other public health emergencies. The Article highlights critical policy and legal issues left unresolved by the NRP, and offers recommendations for the resolution of those issues. The author concludes that, although the NRP is not perfect, it represents a major advance in domestic incident management and provides regular opportunities for review and revision as we learn how to best coordinate the national response to major incidents. A close working relationship between the Departments of Health and Human Services and Homeland Security should enable a unified response to bioterrorism and other public health emergencies in support of state and local efforts.

On January 6, 2005, then-Secretary of Homeland Security Tom Ridge announced the completion of the National Response Plan (NRP).[1] The NRP is intended to establish "a comprehensive all-hazards approach to enhance the ability

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1 Press Release, U.S. Department of Homeland Security (DHS), Department of Homeland Security Secretary Tom Ridge Announces Completion of the National Response Plan (Jan. 6, 2005) [hereinafter Press Release, Completion of the NRP], *available at* www.dhs.gov/dhspublic/interapp/press_release/press_release_0582.xml (last visited May 16, 2005).

of the United States to manage domestic incidents" and provides protocols for "how federal departments and agencies will work together and how the federal government will coordinate with state, local, and tribal governments and the private sector during incidents."[2] Completion of the NRP fulfilled directives from the President[3] and Congress[4] to the Department of Homeland Security (DHS) to consolidate a myriad of existing federal government emergency response plans into one comprehensive plan. The NRP also extends beyond the scope of existing federal plans to encompass the full range of incident management, including prevention, preparedness, response, recovery, and mitigation.[5]

This Article examines the NRP, with particular attention to its approach to bioterrorism. Section I provides an overview of the development, approval process, and overall structure of the NRP. Section II focuses on two key components of the NRP that would facilitate the response to a bioterrorist incident or other biological event: Emergency Support Function (ESF) #8 (Public Health and Medical Services) and the Biological Incident Annex. Because the NRP does not alter or impede the existing legal authorities of departments and agencies,[6] Section III highlights relevant emergency response authorities of the Department of Health and Human Services (HHS), which is the primary federal agency for bioterrorism response under the NRP.[7] Although the NRP makes great strides in consolidating federal response activities into a unified approach, there are several critical legal and policy issues related to emergency preparedness and response that remain unanswered. These include licensing barriers to volunteer healthcare providers

[2] Press Release, DHS, Fact Sheet, National Response Plan (Jan. 6, 2005), *available at* www.dhs.gov/interweb/assetlibrary/NRP_FactSheet_2005.pdf (last visited Apr. 12, 2005).

[3] *See* Press Release, Office of the Press Secretary, The White House, Homeland Security Presidential Directive/HSPD-5, Management of Domestic Incidents (Feb. 28, 2003), *available at* www.whitehouse.gov/news/releases/2003/02/20030228-9.html (last visited May 26, 2005) [hereinafter HSPD-5].

[4] *See* Homeland Security Act of 2002 § 502(6), 6 U.S.C. § 312(6) (2005).

[5] *See* DHS, NATIONAL RESPONSE PLAN 3 (2004), *available at* www.dhs.gov/interweb/assetlibrary/NRP_FullText.pdf [hereinafter NRP].

[6] *Id.* at 2.

[7] *Id.* app. at BIO-1; *see* Press Release, Office of the Press Secretary, The White House, Homeland Security Presidential Directive/HSPD-10, Biodefense for the 21st Century (Apr. 28, 2004), *available at* www.fas.org/irp/offdocs/nspd/hspd-10.html (last visited May 26, 2005) (specifying department and agency responsibilities). While the DHS is the federal government's overall incident manager according to HSPD-5 and the Homeland Security Act of 2002, the NRP details the key roles and responsibilities other departments and agencies have during incident response. *See* NRP, *supra* note 5, at 8-14.

crossing state lines to provide incident assistance and liability protections for those workers. Section IV outlines these issues and recommends solutions. Section V concludes with a discussion of the implications of the NRP and the unanswered legal and policy issues.

I. Background and Overview

A. NRP Drafting and Approval Process

The mandates in the Homeland Security Act of 2002 and Homeland Security Presidential Directive-5 were clear: DHS must consolidate existing federal emergency response plans and establish a single, comprehensive, all-hazards approach to domestic incident management.[8] In order to comply with these directives, DHS convened an interagency writing group to develop the NRP.[9] This group was a subset of the White House Homeland Security Council Domestic Threat Response and Incident Management Policy Coordination Committee, a policy decision group consisting of White House Homeland Security Council staff and senior department and agency representatives.[10]

Using the relevant legislation and executive direction, combined with the principles of the National Strategy for Homeland Security,[11] the writing group developed the NRP with several fundamental guidelines. The plan had to provide for:

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[8] 6 U.S.C. § 312(5)-(6); HSPD-5, *supra* note 3.

[9] See DHS Briefing on National Response Plan 8 (Oct. 15, 2004, Emmitsburg, Md.) (copy on file with author) [hereinafter DHS NRP Briefing].

[10] Press Release, Homeland Security Presidential Directive-1, Organization and Operation of the Homeland Security Council (Oct. 30, 2001), *available at* www.whitehouse.gov/news/releases/2001/10/20011030-1.html (last visited May 26, 2005) [hereinafter HSPD-1].

> [Homeland Security Council] (HSC) Policy Coordination Committees (HSC/PCCs) shall coordinate the development and implementation of homeland security policies by multiple departments and agencies throughout the federal government, and shall coordinate those policies with State and local government. The HSC/PCCs shall be the main day-to-day fora for interagency coordination of homeland security policy. They shall provide policy analysis for consideration by the more senior committees of the HSC system and ensure timely responses to decisions made by the President.

Id. § D.

[11] *See* Off. of Homeland Security, National Strategy for Homeland Security (2002), *available at* www.whitehouse.gov/homeland/book/nat_strat_hls.pdf (last visited Apr. 8, 2005). The White House Office of Homeland Security, the predecessor to the DHS, drafted the national strategy report. *Id.*

- A single comprehensive national approach;
- Federal coordination structures/mechanisms;
- Direction for incorporation of existing plans; and
- A consistent approach to managing incidents.[12]

The writing group circulated the NRP Base Plan for three rounds of stakeholder review and comment and the NRP Annexes for two rounds of review and comment.[13] While the writing team as a whole focused on the base plan, the relevant departments and agencies identified as leads for particular Emergency Support Functions or Incident Annexes drafted their respective sections and adjudicated comments from the review group.[14] The stakeholder review group included federal, state, local, and tribal agencies, private-sector entities, and nongovernmental organizations.[15] This review group submitted over eight thousand comments during the review and revision period.[16] The Homeland Security Council Principals Committee[17] approved the NRP on November 18, 2004,[18] and after time for collecting the relevant signatures[19] and printing, DHS formally announced completion of the plan on January 6, 2005.[20]

B. NRP Overview

1. NRP Structure and Organization

The NRP is organized into five major components across 426 pages.[21]

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[12] HSPD-5, *supra* note 3, § 16.
[13] DHS NRP Briefing, *supra* note 9, at 9.
[14] *Id.*
[15] *See* NRP, *supra* note 5, at i.
[16] DHS NRP Briefing, *supra* note 9, at 9.
[17] The HSC Principals Committee (HSC/PC) is the senior interagency forum under the HSC for homeland security issues. HSPD-1, *supra* note 10, § B. Members of the HSC/PC include: the Secretary of the Treasury; the Secretary of Defense; the Attorney General; the Secretary of HHS; the Secretary of Transportation; the Director of the Office of Management and Budget; the Assistant to the President for Homeland Security (who serves as Chairman); the Assistant to the President and Chief of Staff; the Director of Central Intelligence; the Director of the Federal Bureau of Investigation; the Director of the Federal Emergency Management Agency; and the Assistant to the President and Chief of Staff to the Vice President. *Id.*
[18] *See* Memorandum from Tom Ridge, Secretary, DHS (Dec. 15, 2004) (on file with author) [hereinafter Memorandum from Tom Ridge].
[19] There are thirty-two signatories to the NRP, including thirty federal department and agency heads, the President and Chief Executive Officer of the American Red Cross, and the President of the National Association of Voluntary Organizations Active in Disaster. NRP, *supra* note 5, at v–viii.
[20] Press Release, Completion of the NRP, *supra* note 1.
[21] NRP, *supra* note 5.

- The **Base Plan** describes the overall structure and coordination processes for domestic incident management designed to integrate the efforts and resources of federal, state, local, tribal, private-sector, and nongovernmental organizations.[22] This section includes "planning assumptions, roles and responsibilities, concept of operations, preparedness guidelines, and plan maintenance instructions."[23]
- The **Appendices** include definitions, a list of acronyms, and a list of relevant authorities.[24]
- The **Emergency Support Function (ESF) Annexes** provide the policies, structures, and responsibilities of the federal agencies that organize themselves into fifteen different ESFs to provide support to states, tribes, and other federal agencies or other jurisdictions and entities.[25]
- The **Support Annexes** describe the functional processes and administrative requirements for implementation of the NRP (*e.g.*, financial management, international coordination, logistics management, and private-sector coordination);[26] and
- The **Incident Annexes** describe the specialized application of the NRP to particular hazards or incidents (*e.g.*, biological, catastrophic, and nuclear/radiological).[27]

2. NIMS Provides the Foundation for the NRP

The NRP builds upon the foundation of the National Incident Management System (NIMS),[28] as mandated by the Homeland Security Act of 2002[29] and HSPD-5.[30] NIMS "establishes standardized incident management processes, protocols, and procedures that all responders (Federal, state, tribal, and local) will use to coordinate and conduct response actions."[31] Thus, the NIMS creates a standardized incident command system and

[22] *Id*. at xi.
[23] *Id*.
[24] *Id*.
[25] *Id*.
[26] NRP, *supra* note 5, at xi.
[27] *Id*. at xiii.
[28] The National Incident Management System (NIMS) was created to "provide a consistent nationwide approach for Federal, State, local, and tribal governments to work effectively and efficiently together to prepare for, prevent, respond to, and recover from domestic incidents, regardless of cause, size, or complexity." DHS, NATIONAL INCIDENT MANAGEMENT SYSTEM, at iii (2004) [hereinafter NIMS], *available at* www.dhs.gov/interweb/assetlibrary/NIMS-90-web.pdf (last visited May 26, 2005).
[29] 6 U.S.C. § 312(5) (2005).
[30] HSPD-5, *supra* note 3, § 15.
[31] Press Release, DHS, Fact Sheet: National Incident Management System (NIMS) (Mar. 1, 2004), *available at* www.dhs.gov/dhspublic/display?content=3421 (last visited May 26, 2005).

terminology, no matter who the first responders to an incident are (police, fire, emergency management) or what jurisdictional level they come from (federal, state, tribal, or local). A guiding principle of the NIMS and the NRP is that "[i]ncidents are typically managed at the lowest possible geographic, organizational, and jurisdictional level."[32] Therefore, the intent of the NIMS is not to supplant any local, state, or tribal response, but to create a standardized and consistent approach to incident management at all levels.[33] The NRP builds upon this NIMS framework and outlines the coordination mechanisms for "Federal support to State, local, and tribal authorities; interaction with nongovernmental, private donor, and private-sector organizations; and the coordinated, direct exercise of Federal authorities, when appropriate."[34]

3. The NRP Incorporates Existing Federal Response Plans

The NRP incorporates and supersedes a number of federal emergency response plans:

- Federal Response Plan (FRP);
- Domestic Terrorism Concept of Operations Plan;
- Federal Radiological Emergency Response Plan; and
- Initial National Response Plan.[35]

Although it replaces these plans, the NRP incorporates many concepts and mechanisms associated with them. For example, the ESF structure carries over from the FRP to the NRP. An ESF is a mechanism for federal departments and agencies to organize themselves around a particular function.[36] To illustrate, ESF #6 brings together nineteen federal departments, agencies, and nongovernmental organizations to provide mass care, housing, and human services during an incident.[37] There are fifteen ESFs outlined in the NRP.[38]

The NRP also links together a number of national-level hazard-specific contingency plans that remain in effect, but will be updated to reflect the NRP's coordination structures, such as the National

[32] NRP, *supra* note 5, at 6.
[33] NIMS, *supra* note 28, at iii.
[34] NRP, *supra* note 5, at i.
[35] *Id*. at 1.
[36] *Id*. app. at ESF-i.
[37] *Id*. app. at ESF #6-1.
[38] *See id*. at xii.

Oil and Hazardous Substances Pollution Contingency Plan.[39] These plans can be implemented independently during localized incidents or concurrently with the NRP during national incidents.[40]

4. NRP and Incidents of National Significance

The NRP introduces a new concept into the federal response architecture by distinguishing between high-impact incidents that require coordination by the Secretary of Homeland Security, known as Incidents of National Significance, and "the majority of incidents occurring each year that are handled by responsible jurisdictions or agencies through other established authorities and existing plans" and do not require DHS coordination.[41] Notably, the plan provides the response mechanisms not just for actual Incidents of National Significance, but also for potential Incidents of National Significance (*e.g.*, credible threats of terrorism), which allows for pre-event planning and asset deployment.[42]

Pursuant to the Homeland Security Act of 2002 and HSPD-5, the Secretary of Homeland Security is the principal federal official (PFO) for domestic incident management in certain situations.[43] The DHS Secretary can declare an event to be an Incident of National Significance, thereby serving as the overall federal incident management coordinator, when any one of four conditions applies:

- A federal department or agency acting under its own authority has requested the assistance of the Secretary of DHS;
- The resources of state and local authorities are overwhelmed and federal assistance has been requested by the appropriate state and local authorities (*e.g.*, an event that results in a Presidential declaration of major disaster or emergency under the Robert T. Stafford Disaster Relief and Emergency Assistance Act[44] [Stafford Act] or a catastrophic event);[45]

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[39] *See* NRP, *supra* note 5, at 10–11.
[40] *Id*. at 10.
[41] *Id*. at 3.
[42] *See id*.
[43] 6 U.S.C. § 312(3) (2005); HSPD-5, *supra* note 3, § 4.
[44] 42 U.S.C. §§ 5121–5205 (2005).
[45] "A catastrophic event is any natural or manmade incident, including terrorism, that results in extraordinary levels of mass casualties, damage, or disruption severely affecting the population." NRP, *supra* note 5, at 43.

- More than one federal department or agency has become substantially involved in responding to the incident (*e.g.*, this includes credible threats of an imminent terrorist attack, actual acts of terrorism; or threats related to high-profile, large-scale events that present high-probability targets such as National Special Security Events [NSSEs][46] and other special events as determined by the Secretary of Homeland Security, in coordination with other federal departments and agencies); or
- The Secretary of DHS has been directed to assume responsibility for managing a domestic incident by the President.[47]

5. NRP and Stafford Act/Non-Stafford Act Incidents

Another significant advance in the NRP is its potential applicability to Incidents of National Significance whether or not a Presidential declaration of major disaster[48] or emergency[49] has occurred under the Stafford Act.[50] Under the Stafford Act,

[46] If an event is designated a National Special Security Event (NSSE), the Secret Service assumes the role of lead federal agency for the design and implementation of the security plan and federal resources are deployed to maintain the level of security needed for the event. Press Release, DHS, Fact Sheet: National Special Security Events Memorial Service for President Reagan (June 6, 2004), *available at* www.dhs.gov/dhspublic/display?content=3703 (last visited on Apr. 17, 2005). Examples of NSSEs include a Presidential Inauguration, State of the Union address, or State funeral. *Id*.

[47] HSPD-5, *supra* note 3, § 4; NRP, *supra* note 5, at 4.

[48] Under the Stafford Act,

> "Major disaster" means any natural catastrophe (including any hurricane, tornado, storm, high water, winddriven water, tidal wave, tsunami, earthquake, volcanic eruption, landslide, mudslide, snowstorm, or drought), or, regardless of cause, any fire, flood, or explosion, in any part of the United States, which in the determination of the President causes damage of sufficient severity and magnitude to warrant major disaster assistance under this chapter to supplement the efforts and available resources of States, local governments, and disaster relief organizations in alleviating the damage, loss, hardship, or suffering caused thereby.

42 U.S.C. § 5122(2).

[49] Under the Stafford Act,

> "Emergency" means any occasion or instance for which, in the determination of the President, federal assistance is needed to supplement State and local efforts and capabilities to save lives and to protect property and public health and safety, or to lessen or avert the threat of a catastrophe in any part of the United States.

Id. § 5122(1).

[50] Pursuant to HSPD-5, the Secretary of Homeland Security declares Incidents of National Significance after consultation with other departments and agencies, if appropriate. NRP, *supra* note 5, at 4.

a state[51] governor[52] can request a Presidential declaration if an incident is "of such severity and magnitude that effective response is beyond the capabilities of the State and the affected local governments and that Federal assistance is necessary."[53] Once such a Presidential declaration is made, states become eligible for a variety of federal response and recovery assistance programs through the Federal Disaster Relief Fund.[54] Perhaps most importantly for federal-to-federal support during Stafford Act incidents, however, is that federal departments and agencies are reimbursed by DHS/FEMA for expenditures incurred in providing support to the affected state.[55]

Prior to the NRP, a federal department requesting assistance from another federal department would have to work out a mechanism for reimbursement for the assistance provided.[56] This led to a patchwork of interagency agreements with no consistency. The Financial Management Support Annex of

[51] Under the Stafford Act, "State means any State of the United States, the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands." 42 U.S.C. § 5122(4).

[52] The definition of "Governor" includes the chief executive of any jurisdiction defined as a "state" under the Stafford Act. *Id*. § 5122(5).

[53] *Id*. § 5170. As part of the request, the Governor must: (1) take appropriate action under State law and direct execution of the State's emergency plan, (2) furnish information on the nature and amount of State and local resources that have been or will be committed to alleviating the results of the disaster, (3) provide an estimate of the amount and severity of damage and the impact on the private and public sector, and (4) provide an estimate of the type and amount of assistance needed under the Stafford Act. Fed. Emergency Mgmt. Agency, A Guide to The Disaster Declaration Process and Federal Disaster Assistance 1 (2003), *available at* www.fema.gov/pdf/rrr/dec_proc.pdf (last visited May 27, 2005). In addition, the Governor must certify that state and local government obligations and expenditures will comply with all applicable cost-sharing requirements. *Id*.

[54] Fed. Emergency Mgmt. Agency, *supra* note 53, at 1. Disaster assistance under the Stafford Act falls into three categories:

> (1) Individual Assistance—aid to individuals and households; (2) Public Assistance—aid to public (and certain private non-profit) entities for certain emergency services and the repair or replacement of disaster-damaged public facilities; and (3) Hazard Mitigation Assistance—funding for measures designed to reduce future losses to public and private property.

Id. at 2.

[55] 42 U.S.C. § 5147.

[56] This was typically done through an interagency agreement under the Economy Act, 31 U.S.C. § 1535 (2005).

the NRP includes a Memorandum of Agreement and Request Form that all signatories to the NRP agreed to use for federal-to-federal requests during Incident of National Significance for which no Stafford Act declaration is made.[57] Thus, the NRP will allow consistency in the agreements and financial arrangements between federal partners responding to non-Stafford Act Incidents of National Significance.

6. NRP and Catastrophic Incidents

The NRP also provides an approach for federal support during catastrophic incidents that expedites or suspends (if necessary) the standard Stafford Act request process.[58] The NRP defines a catastrophic event as "any natural or manmade incident, including terrorism, that results in extraordinary levels of mass casualties, damage, or disruption severely affecting the population, infrastructure, environment, economy, national morale, and/or government functions."[59] The plan calls for a proactive federal response that allows for the rapid delivery of resources and assets (including special teams, equipment, and supplies) that aid in saving lives or containing the incident.[60] The catastrophic event procedures include:

> - The pre-identification of federal assets and capabilities;
> - The strategic location of pre-identified assets for rapid deployment; and
> - The use of pre-scripted mission assignments, . . . or individual agency authority and funding, to expedite deployment upon notification by DHS (in accordance with procedures established in the NRP Catastrophic Incident Supplement)[61] of a potential catastrophic event.[62]

The NRP notes that "[p]rotocols for proactive Federal response are most likely to be implemented for catastrophic events involving chemical, biological, radiological, nuclear, or high-yield explosive weapons of mass destruction, or large-

[57] NRP, *supra* note 5, app. at FIN-10 to -16.
[58] *Id*. at 44.
[59] *Id*. at 43.
[60] *Id*. at 44.
[61] The NRP contains a Catastrophic Incident Annex, which is an abbreviated version of "[a] more detailed and operationally specific NRP Catastrophic Incident Supplement (NRP-CIS) that is classified 'For Official Use Only'" and will exist independently of the NRP Base Plan and annexes. *Id*. app. at CAT-1.
[62] NRP, *supra* note 5, at 44.

magnitude earthquakes or other natural or technological disasters in or near heavily populated areas."[63]

7. NRP Coordination Structures

In order to facilitate domestic incident management, the NRP contains a number of coordination structures that range from the national level down through the regional level to the field level of operations.[64] These structures allow the federal government to execute the incident management responsibilities of the President through the federal departments and agencies, and to integrate the response efforts across jurisdictions and entities (federal, state, local, tribal, nongovernmental organization, and private sector).[65] Although a detailed description of these coordination structures is beyond the scope of this Article,[66] it is worth highlighting several of them.

- Interagency Incident Management Group (IIMG) (national level): The IIMG is a "Federal headquarters-level multiagency coordination entity that facilitates strategic Federal domestic incident management for Incidents of National Significance."[67] When activated, the IIMG synthesizes information, frames issues, and makes recommendations to the Secretary of DHS on policy issues, actions to take in response to threats, operational issues, priorities for use or allocation of federal resources, and develops strategies for implementing existing policies and provides incident information to DHS and the White House to facilitate policymaking.[68]
- Homeland Security Operations Center (HSOC) (national level): "The HSOC is the primary national hub for domestic incident management operational coordination and situational awareness. The HSOC is a standing 24/7 interagency organization fusing law enforcement, national intelligence, emergency response, and private sector reporting. The HSOC facilitates homeland security information-sharing and operational coordination with other Federal, State, local, tribal, and non-governmental E[mergency] O[perations] C[enter]s."[69]

[63] *Id*. at 43.
[64] *See*, *e.g.*, *id*. at 19.
[65] *Id*. at 15.
[66] *See id*. at 15–40 (describing in detail NRP's coordination structures).
[67] NRP, *supra* note 5, at 22.
[68] *Id*. at 22–23.
[69] *Id*. at 24.

- National Response Coordination Center (NRCC) (national level): "The NRCC is a multiagency center that provides overall Federal operational response coordination for Incidents of National Significance and emergency management program implementation. DHS/EPR/FEMA maintains the NRCC as a functional component of the HSOC in support of incident management operations."[70] NRCC's activities include:

  - Monitoring the preparedness status of national-level emergency response teams and resources;
  - In coordination with Regional Response Coordination Centers (RRCCs), initiating mission assignments or reimbursable agreements to activate other federal departments and agencies through the ESF structure or independently;
  - Activating and deploying national-level response assets; and
  - Coordinating operational response and resource allocation planning with the appropriate federal departments and agencies, RRCCs, and the Joint Field Office (JFO).[71]

- The Regional Response Coordination Center (RRCC) (regional): The RRCC is "activated to coordinate regional response efforts, establish Federal priorities, and implement local Federal program support until a JFO is established in the field and the [appropriate coordinators (*e.g.*, the PFO)] can assume their NRP responsibilities. The RRCC establishes communications with the affected state emergency management agency and the NRCC coordinates deployment of the Emergency Response Team-Advance Element (ERT-A) to field locations, assesses damage information, develops situation reports, and issues initial mission assignments."[72]
- JFO Coordination Group and JFO local/incident level: The JFO Coordination Group directs the JFO and may include the PFO, the Senior Law Enforcement Officer, the Federal Coordinating Officer, or other senior federal officials with primary jurisidictional authority for the incident.[73] The JFO Coordination Group follows NIMS incident command structures and principles and "functions as a multiagency

[70] *Id*. at 25.
[71] *Id*. at 26.
[72] NRP, *supra* note 5, at 27.
[73] *Id*. at 33.

coordination entity and works jointly to establish priorities (single or multiple incidents) and associated resource allocation, resolve agency policy issues, and provide strategic guidance to support Federal incident management activities."[74] The JFO "provides a central location for coordination of Federal, State, local, tribal, nongovernmental, and private-sector organizations with primary responsibility for threat response and incident support."[75] Both the JFO Coordination Group and the composition of the JFO are flexible and can adapt depending on the type of incident (*e.g.*, terrorism, natural disaster, NSSEs).[76]

For all Incidents of National Significance, the Secretary of DHS serves as or designates a PFO, who serves as the Secretary's primary point of contact and works to ensure that incident management efforts are coordinated.[77] The PFO does not, however, become the local incident commander or direct the incident command structure or other federal officials (including law enforcement).[78]

Although it appears that the NRP creates new layers of incident management, many of the referenced coordination structures existed under different names or forms prior to the NRP (*e.g.*, the JFO was previously known as the Disaster Field Office),[79] and the increased robustness of each coordination structure reflects an intent to standardize a comprehensive all-hazards approach to domestic incident management at a time when the threat scenarios are more complicated than ever before.[80]

8. NRP Implementation Timelines

The NRP provides for a 120-day implementation timeline and review and re-issuance cycles in the future.[81] The Secretary of DHS set the implementation period start date as December 15, 2004.[82]

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[74] *Id*. at 33.
[75] *Id*. at 28.
[76] *See id*. at 28–32. Figures 6 through 9 illustrate possible JFO organizational structures, depending on the type of threat scenario and incident. *Id*. at 28–32.
[77] NRP, *supra* note 5, at 33–34.
[78] *Id*. at 33.
[79] *Id*. at 28.
[80] *See id*. at 1. "These complex and emerging 21st century threats and hazards demand a unified and coordinated national approach to domestic incident management." *Id*.
[81] *Id*. at ix.
[82] *See* Memorandum from Tom Ridge, *supra* note 18.

During the first sixty days of implementation, federal departments and agencies were expected to familiarize themselves with the NRP, modify their training programs, and designate representatives for the NRP coordination structures (*e.g.*, IIMG, NRCC).[83] From 60 to 120 days after the implementation date, federal departments and agencies were expected to modify existing interagency plans to align with the NRP and conduct necessary training.[84] The full implementation deadline (120 days) was April 14, 2005, and from this date until December 15, 2005, federal departments and agencies are expected to conduct systematic assessments/exercises of the NRP coordinating structures, processes, and protocols as they are implemented.[85] The plan provides for a one-year review to assess the implementation process and provide recommended revisions to the plan.[86] Thereafter, the NRP will enter a four-year review and re-issuance cycle.[87]

II. ESF #8 (Public Health and Medical Services) and the Biological Incident Annex

Two key components of the NRP provide the framework for the response to a biological incident, including bioterrorism. The ESF #8 Annex (ESF #8) provides the general "mechanism for coordinated Federal assistance to supplement State, local, and tribal resources in response to public health and medical care needs."[88] The Biological Incident Annex builds upon ESF #8 and provides additional details regarding a "response to a disease outbreak of known or unknown origin requiring Federal assistance."[89]

A. ESF #8 (Public Health and Medical Services)

ESF #8 brings together fifteen federal departments and agencies and the American Red Cross to coordinate the provision of public health and medical support for federal-to-federal

[83] *See* NRP, *supra* note 5, at ix.
[84] *See id*.
[85] *Id*.
[86] *Id*.
[87] *Id*.
[88] NRP, *supra* note 5, app. at ESF #8-1.
[89] *Id*. app. at BIO-1.

assistance and federal assistance to state, local, and tribal jurisdictions.[90]

Through the ESF #8 structure, the partners bring to bear significant public health and medical resources. HHS is the primary agency for ESF #8 coordination.[91] The Secretary of HHS coordinates the ESF #8 preparedness, response, and recovery actions through the Assistant Secretary for Public Health Emergency Preparedness (ASPHEP).[92]

ESF #8 resources can be activated through the Stafford Act,[93] the Public Health Service Act,[94] or in accordance with the memorandum for federal-to-federal support included in the NRP Financial Management Support Annex.[95] ESF #8 support focuses on the following core functional areas:

- Assessment of public health/medical needs (including behavioral health);
- Public health surveillance;
- Medical care personnel; and
- Medical equipment and supplies.[96]

In order to fulfill requests for support from federal departments and agencies or state, local, or tribal jurisdictions, ESF #8 uses resources available from HHS (*e.g.*, the Centers for Disease Control and Prevention [CDC], the U.S. Public Health Service Commissioned Corps, the Strategic National Stockpile of pharmaceuticals and medical equipment) and ESF #8 partner organizations (*e.g.*, the DHS, Department of Defense [DoD], Veterans Affairs [VA], and the American Red Cross).[97] For example, DHS can deploy the medical teams of the National Disaster Medi-

[90] *See id*. app. at ESF #8-1. The ESF #8 partners are the HHS, Agriculture, Defense (DoD), Energy, Homeland Security, Interior, Justice, Labor, State, Transportation, Veterans Affairs (VA), the Environmental Protection Agency, General Services Administration, U.S. Agency for International Development, U.S. Postal Service, and the American Red Cross. *Id*.
[91] *Id*. app. at ESF #8-2.
[92] NRP, *supra* note 5, app. at ESF #8-2.
[93] 42 U.S.C. §§ 5121–5205 (2005).
[94] 42 U.S.C. §§ 201–300hh-11 (2005).
[95] NRP, *supra* note 5, app. at ESF #8-1.
[96] *Id*.
[97] *See id*.

cal System (NDMS)[98] either under its own authority[99] or at the request of HHS as the coordinator of ESF #8.[100] The VA, when requested, can deploy "available medical, surgical, mental health, and other health service support assets."[101]

Once ESF #8 is activated, the ASPHEP alerts identified personnel to represent ESF #8, as required,[102] on the NRP coordination structures outlined in Section I of this Article. These include, for example, the NRCC, the IIMG, and the RRCC/JFO.[103] While these personnel are activated and deployed to the relevant coordination structures, HHS also notifies and requests ESF #8 partner organizations to participate in headquarters coordination activities, including providing liaisons to the Secretary of HHS's Operations Center, a 24/7 communications hub from which the ASPHEP (or a designee) can coordinate ESF #8 operations.[104]

Throughout operations, ESF #8 coordinates and communicates with federal (at the headquarters and regional levels), state, local, and tribal partners to determine the ongoing public health and medical needs.[105] The ESF #8 structure also allows for consultation with public health and medical subject matter experts as necessary.[106]

[98] *Id*. app. at ESF #8-4. The NDMS is a partnership of four ESF #8 partners: HHS, DHS, DoD and VA. The system has three components: teams of medical personnel who have signed up to be activated as federal intermittent employees when necessary (and the necessary team equipment and supplies); a patient transport system that moves affected individuals from an incident scene to unaffected areas; and a system of participating hospitals that provide in-patient or "definitive" care to individuals affected by the incident. *See* DHS, National Disaster Medical System, *at* www.ndms.dhhs.gov/ (last visited Mar. 20, 2005) (providing a description of the NDMS).

[99] 42 U.S.C. § 300hh-11(b) (2002) (outlining the authority to activate the NDMS). These functions and authorities were transferred to DHS in the Homeland Security Act of 2002 § 503, 6 U.S.C. § 313 (2005).

[100] NRP, *supra* note 5, app. at ESF #8-10.

[101] *Id*. app. at ESF #8-12. The VA's ability to assist is subject to the availability of resources and funding (Stafford Act or otherwise) and must be consistent with the VA mission to provide priority services to veterans. *Id*.

[102] *Id*. app. at ESF #8-3.

[103] *Id*.

[104] NRP, *supra* note 5, app. at ESF #8-3. The Secretary of HHS's Operations Center maintains frequent contact with the HSOC for situational awareness and response coordination. *Id*. at 2.

[105] *Id*.

[106] *Id*.

B. Biological Incident Annex

The Biological Incident Annex builds upon the processes in the NRP Base Plan and ESF #8 and details more specific actions, roles, and responsibilities associated with the "response to a disease outbreak of known or unknown origin requiring Federal assistance."[107] The Annex specifies "biological incident response actions including threat assessment notification procedures, laboratory testing, joint investigative/response procedures, and activities related to recovery."[108]

> The broad objectives of the Federal Government's response to a biological terrorism event, pandemic influenza, emerging infectious disease, or novel pathogen outbreak are to:
>
> - Detect the event through disease surveillance and environmental monitoring;
> - Identify and protect the population(s) at risk;
> - Determine the source of the outbreak;
> - Quickly frame the public health and law enforcement implications;
> - Control and contain any possible epidemic (including providing guidance to State and local public health authorities);
> - Augment and surge public health and medical services;
> - Track and defeat any potential resurgence or additional outbreaks; and
> - Assess the extent of residual biological contamination and decontaminate as necessary.[109]

Unlike many types of incidents covered by the NRP, a biological terrorist attack may be covert and not immediately detected, in which case "the first evidence of dissemination of an agent may be the presentation of disease in humans or animals."[110]

> A terrorist-induced infectious disease outbreak initially may be indistinguishable from a naturally occurring outbreak; moreover, depending upon the particular agent and associated symptoms, several days could pass before public health and medical authorities even suspect that terrorism may be the

[107] *Id*. app. at BIO-1.
[108] *Id*.
[109] NRP, *supra* note 5, app. at BIO-1.
[110] *Id*. app. at BIO-2.

> cause. In such a case, criminal intent may not be apparent until some time after illnesses are recognized.[111]

"HHS serves as the Federal Government's primary agency for the public health and medical preparation and planning for and response to a biological terrorism attack or naturally occurring outbreak."[112] Consistent with the NRP and NIMS, however, the Biological Incident Annex explicitly acknowledges that "State, local, and tribal governments are primarily responsible for detecting and responding to disease outbreaks and implementing measures to minimize the health, social, and economic consequences of such an outbreak."[113]

A potential bioterrorism incident has clear law enforcement implications, and the Federal Bureau of Investigation (FBI) coordinates the investigation of suspected criminal activities.[114] The Annex outlines notification requirements for law enforcement purposes. Any federal department or agency that "becomes aware of an overt threat involving biological agents or indications that instances of disease may not be the result of natural causes [notifies the FBI's Weapons of Mass Destruction Operations Unit]."[115] The FBI then makes follow-on notifications to the DHS, HSOC, and the National Counterterrorism Center.[116] Such notification and communication chains are spelled out explicitly throughout the NRP, with the intent of providing a consistent and comprehensive approach to making all relevant entities aware of events.

HHS collaborates with the FBI in the proper handling of any materials that may have evidentiary implications.[117] The Laboratory Response Network (LRN)[118] is used to test samples for the presence of biological threat agents. "The LRN provides for rapid public health assessment of the potential for human illness associated with exposure and . . . addresses the need for law en-

[111] *Id*.
[112] *Id*.
[113] *Id*.
[114] NRP, *supra* note 5, app. at BIO-3.
[115] *Id*. app. at BIO-2.
[116] *Id*.
[117] *Id*. app. at BIO-3.
[118] The CDC established the LRN through a collaborative effort with the FBI and the Association of Public Health Laboratories. LRN, CDC, The Laboratory Response Network: Partners in Preparedness, *at* www.bt.cdc.gov/lrn (last visited Mar. 23, 2005). The LRN became operational in August 1999, and "its objective was to ensure an effective laboratory response to bioterrorism by helping to improve the nation's public health laboratory infrastructure, which had limited ability to respond to bioterrorism." *Id*.

forcement notification necessary to initiate threat assessment for criminal intent, and chain of custody procedures."[119]

If a positive result is obtained by an LRN laboratory on an environmental sample submitted by the FBI or other designated law enforcement personnel, the LRN notifies the FBI, which "convenes an initial conference call with the local FBI and HHS to review the results, assess the preliminary information and test results, and arrange for additional testing."[120] "HHS provides guidance on protective measures such as prophylactic treatment" and works with ESF #8 partner organizations to "support the determination of the contaminated area, decisions on whether to shelter in place or evacuate, and [technical advice regarding] decontamination of people, facilities, and outdoor areas."[121]

> Once notified of a threat or disease outbreak that requires or potentially requires significant Federal public health and/or medical assistance, HHS convenes a meeting of the ESF #8 organizations and HHS Operating Divisions . . . to assess the situation and determine the appropriate public health and medical actions. The immediate task following any notification is to identify the population affected and at risk and the geographic scope of the incident. The initial public health and medical response includes some or all of the following actions:
>
> - Targeted epidemiological investigation (e.g., contact tracing);
> - Intensified surveillance within healthcare settings for patients with certain clinical signs and symptoms;
> - Intensified collection and review of potentially related information (e.g., contacts with nurse call lines, laboratory test orders, school absences, and over-the-counter pharmacy sales); and
> - Organization of Federal public health and medical response assets (in conjunction with State, local, and tribal officials) to include personnel, medical supplies, and materiel (e.g., the Strategic National Stockpile (SNS)).[122]

[119] NRP, *supra* note 5, app. at BIO-4.
[120] *Id*. app. at BIO-5.
[121] *Id*.
[122] *Id*. app. at BIO-6.

III. HHS Legal Authorities

HHS relies on a number of authorities to carry out its emergency preparedness and response activities under the NRP and applicable law. The NRP does not alter or impede these existing legal authorities.[123] This section highlights some, but not all, of the relevant emergency authorities of HHS.

A. Public Health Service Act (PHS Act)[124]

1. Public Health Emergency Declaration

Under the PHS Act, the Secretary of HHS has broad authority to respond to public health emergencies.[125] A response might include directing the deployment of the U.S. Public Health Service Commissioned Corps or other HHS response teams and assets, including those from the CDC, the Food and Drug Administration (FDA), and the National Institutes of Health.[126] Under Section 319 of the act,[127] the Secretary of HHS can declare a public health emergency and take appropriate steps to respond to such an emergency.[128] In order to make such a declaration, the Secretary of HHS must find (after consulting with such public health authorities "as may be necessary"[129]) that: "(1) a disease or disorder presents a public health emergency; or (2) a public health emergency, including significant outbreaks of infectious diseases or bioterrorist attacks, otherwise exists."[130]

Once such a declaration has been made, the Secretary of HHS "may take such action as may be appropriate to respond to the public health emergency."[131] In addition to deploying teams and resources from the department, the Secretary of HHS can

[123] NRP, *supra* note 5, at 2.
[124] 42 U.S.C. §§ 201–300hh-11.
[125] *See id.*
[126] HHS has twelve operating divisions: the Office of the Secretary (including the Office of the Assistant Secretary of Health, the Office of the Surgeon General and the Office of Public Health Emergency Preparedness), Administration on Aging, Administration for Children and Families, Agency for Healthcare Research and Quality, CDC, Centers for Medicare and Medicaid Services (CMS), Food and Drug Administration, Health Resources and Services Administration, Indian Health Service, National Institutes of Health, Program Support Center and the Substance Abuse and Mental Health Services Administration. HHS, GUIDE TO INFORMATION RESOURCES, *at* www.hhs.gov/about/infoguid.html#pub (last visited Mar. 21, 2005).
[127] 42 U.S.C. § 247d (2005).
[128] *Id.* § 247d(a).
[129] *Id.*
[130] *Id.*
[131] *Id.*

make grants, provide awards for expenses, enter into contracts, and conduct and support investigations "into the cause, treatment, or prevention of a disease or disorder" that caused the emergency.[132] Such a declaration also makes available resources from the Public Health Emergency Fund, to which Congress may make appropriations as necessary and which supplements other available public funds for emergency response such as the Disaster Relief Fund under the Stafford Act.[133]

2. Isolation and Quarantine

States have primary authority for public health matters within their borders, including isolation and quarantine.[134] This authority derives from the states' powers to protect the health and safety of their citizens, known as the "police powers."[135] The police powers are reserved to the states under the Tenth Amendment to the U.S. Constitution.[136] Despite the federal presence in public health, "the states and localities have had the predominant public responsibility for population-based health services since the founding of the republic."[137]

When the matter involves isolation and quarantine of individuals seeking to enter the U.S. or travel across state lines, the federal government has jurisdiction. Section 361 of the PHS Act[138] authorizes the Secretary of HHS[139] to "make and enforce such regulations as in his judgment are necessary to prevent the

[132] 42 U.S.C. § 247d(a).

[133] *Id.* §§ 247d(b)(1), 247d(c). A public health emergency declaration lasts ninety days but can be terminated earlier or extended by the Secretary if necessary. *Id.* § 247d(a)(2). The Secretary must notify Congress within forty-eight hours of making the declaration. *Id.*

[134] Although the terms are often used interchangeably, there is a difference between isolation and quarantine. Isolation refers to separating individuals who are known to have an infectious illness from those who are healthy and restricting the infected person's movement in order to prevent the spread of the illness. Quarantine refers to the separation and movement restriction of people who are not yet ill but who have been exposed to an infectious agent and therefore may become ill and infectious. Nat'l Ctr. for Infectious Diseases, CDC, Legal Authorities for Isolation and Quarantine (2004), *available at* www.cdc.gov/ncidod/dq/sars_facts/factsheetlegal.pdf (last visited May 21, 2005).

[135] Lawrence O. Gostin, Public Health Law: Power, Duty, Restraint 26–27, 47–51 (2000).

[136] *Id.* at 26–27.

[137] *Id.* at 47.

[138] 42 U.S.C. § 264 (2005).

[139] Section 361 refers to the Surgeon General, but under Reorganization Plan No. 3 of 1966, all references to the Surgeon General are deemed to be references to the Secretary of HHS. *See* 42 U.S.C. § 202 note (2005) (1966 Reorganization Plan No. 3).

introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or possession."[140] To carry out and enforce such regulations, the Secretary of HHS may inspect, disinfect, or destroy infected animals or articles that pose a danger to humans.[141] The PHS Act further authorizes the Secretary of HHS to apprehend and examine "any individual reasonably believed to be infected with a communicable disease" who is moving or about to move from one state to another or who poses a probable cause of infection to individuals who will be moving from one state to another.[142] This broad authority applies when the communicable disease suspected is one specified in an Executive Order of the President that is based on a recommendation of the Secretary of HHS in consultation with the Surgeon General.[143] Executive Order No. 13295 permits apprehension, detention, or conditional release of individuals to prevent transmission of Cholera, Diphtheria, infectious Tuberculosis, Plague, Smallpox, Yellow Fever, Viral Hemorrhagic Fevers, and Severe Acute Respiratory Syndrome.[144] This order was amended on April 1, 2005, to include "[i]nfluenza caused by novel or reemergent influenza viruses that are causing, or have the potential to cause, a pandemic."[145]

Federal law specifies that U.S. Customs and Coast Guard officers have a duty to assist in the enforcement of federal quarantine rules and regulations.[146] In addition, Customs officers, Coast Guard officers, and military officers commanding any coastal station are obligated to observe state quarantines related to incoming ships and, when directed by the Secretary of HHS, to aid in the enforcement of such quarantines.[147] Finally, the Secretary of HHS is authorized to accept assistance from state and local authorities in enforcing federal quarantine regulations, and the Secretary of HHS can assist state and local governments in enforcing their own quarantine regulations and otherwise

[140] 42 U.S.C. § 264(a).
[141] *Id.*
[142] *Id.* § 264(d)(1).
[143] *Id.* § 264(b).
[144] Exec. Order No. 13295, 68 Fed. Reg. 17,255 (Apr. 4, 2003). HHS, through the CDC's Division of Global Migration and Quarantine (DGMQ), maintains quarantine stations at eight U.S. airports (Atlanta, Miami, New York (JFK), Chicago, Honolulu, San Francisco, Los Angeles, and Seattle-Tacoma). DGMQ, CDC, Quarantine Stations, *at* www.cdc.gov/ncidod/dq/quarantine_stations.htm (last visited May 21, 2005).
[145] Exec. Order No. 13375, 70 Fed. Reg. 17,299 (Apr. 5, 2005).
[146] *See* 42 U.S.C. § 268(b) (2005).
[147] *Id.* § 97.

controlling the spread of communicable diseases.[148] Based on their respective authorities, states and the federal government can have concurrent jurisdiction over a quarantine issue.

3. Strategic National Stockpile (SNS)

The PHS Act also directs the Secretary of HHS to coordinate with DHS in maintaining a stockpile of "drugs, vaccines and other biological products, medical devices and other supplies" that are necessary to protect the nation during a bioterrorist attack or other public health emergency.[149] "Stockpile" is defined as: (1) physical accumulation (at one or more locations) of the described supplies, or (2) a contractual agreement between the Secretary of HHS and a vendor or vendors under which each vendor agrees to provide the described supplies to the Secretary of HHS.[150] The SNS program staff is housed at the CDC in Atlanta, and the program maintains the capability to deliver SNS materiel to any state in the U.S. within twelve hours.[151]

The recent history of the SNS (along with the transition of the NDMS) shows the confusion and potential tension between HHS and DHS in the division of responsibilities and authorities for protecting public health. The Homeland Security Act of 2002 transferred the SNS from HHS to DHS.[152] Less than two years later, the Project BioShield Act of 2004 transferred the SNS back to HHS.[153]

4. Credentialing of Health Professionals

Among the critical needs during a large-scale public health emergency will be a sufficient number of healthcare professionals to provide services to those affected by an incident. The PHS Act directs the Secretary of HHS to establish and maintain a system for advance registration of health professionals to verify credentials, licenses, accreditations, and hospital privileges when such professionals volunteer to provide services during public health emergencies.[154] In establishing the system, HHS must provide for an electronic database[155] and provisions

[148] *Id*. § 243(a).
[149] *Id*. § 247d-6b(a)(1).
[150] *Id*. § 247d-6b(e).
[151] CDC, Strategic National Stockpile (2005), *at* www.bt.cdc.gov/stockpile/index.asp (last visited May 21, 2005).
[152] 6 U.S.C. § 313 (2005).
[153] 42 U.S.C. § 247d-6b.
[154] *Id*. § 247d-7b(a).
[155] *Id*.

for "promptness and efficiency of the system in collecting, storing, updating, and disseminating information on the credentials, licenses, accreditations, and hospital privileges of [the] volunteers."[156] The HHS Health Services and Resources Administration (HRSA) is implementing this system, known as the Emergency System for Advance Registration of Volunteer Healthcare Providers (ESAR-VHP).[157]

In developing the system, HHS is awarding grants and providing technical assistance to states and other public or nonprofit private entities for activities relating to the verification system.[158] Under the program, the Secretary of HHS "may encourage each State to provide legal authority during a public health emergency for health professionals authorized in another State to provide . . . such health services in the State."[159] Because states have jurisdiction over healthcare provider licensing and credentialing within their own borders under the police powers, the Secretary of HHS is not authorized to issue requirements regarding provisions by states of credentials, licenses, accreditations, or hospital privileges.[160]

B. Waiver of Regulatory Requirements

A public health emergency declaration (or Stafford Act declaration) also triggers additional HHS emergency authorities, including waivers of certain Medicare, Medicaid, and Food, Drug and Cosmetics Act requirements.[161] For example, during a declared emergency, the Secretary of HHS can waive:[162]

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[156] *Id*. § 247d-7b(b).

[157] *See* Melissa Sanders, Update on State and Local Preparedness, Secretary's Council on Public Health Preparedness (May 3, 2004), *available at* www.hhs.gov/ophep/presentation/ SANDERS_Sec_Council_May_2004.pdf (last visited Apr. 9, 2005); *see also* Marilyn Biviano, Emergency System for Advance Registration of Volunteer Health Professionals (ESAR-VHP) Plan, Greater New York Hospital Association Briefing on Utilizing Volunteers During Disasters (Aug. 9, 2004), *available at* www.gnyha.org/eprc/general/presentations/20040809_ESAR-VHP.pdf (last visited Apr. 9, 2005).

[158] *See* Biviano, *supra* note 157.

[159] 42 U.S.C. § 247d-7b(d).

[160] *Id*. § 247d-7b(e).

[161] *See id*. § 1320b-5. These provisions were added by section 143 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Pub. L. No. 107-188, 116 Stat. 594, 627–29, and further amended by section 9 of the Project BioShield Act of 2004, Pub. L. No. 108-276, 118 Stat. 835, 863–64.

[162] Prior to waiving any of these requirements, the Secretary of HHS must notify Congress. *See* 42 U.S.C. § 1320b-5(d).

- Conditions of participation in Medicare or Medicaid for individual healthcare providers;[163]
- "[R]equirements that physicians and other health care professionals be licensed in the State in which they provide such services, if they have equivalent licensing in another State and are not affirmatively excluded from practice in that State or in any State a part of which is included in the emergency area;"[164]
- Actions under the Emergency Medical Treatment and Emergency Labor Act (EMTALA)[165] for (1) an inappropriate transfer of a patient that has not been stabilized (if the transfer is necessitated by the circumstances of the declared emergency) or (2) the direction of an individual to obtain a medical screening exam at another location under a state emergency preparedness plan;[166]
- Sanctions under the Stark law's prohibitions on certain physician referrals;[167] and
- Sanctions and penalties that arise from noncompliance with certain privacy requirements under the Health Insurance Portability and Accountability Act of 1996 (HIPAA).[168]

[163] *Id*. § 1320b-5(b)(1)(B).
[164] *Id*. § 1320b-5(b)(2).
[165] 42 U.S.C. § 1395dd (2005).
[166] *Id*. § 1320b-5(b)(3). The application of EMTALA during a public health emergency has caused much confusion since the October 2001 anthrax attacks. In a November 2001 letter, CMS issued guidance suggesting that EMTALA's screening and transfer requirements would not apply during a bioterrorist incident. *See* Sara Rosenbaum & Brian Kamoie, *Finding a Way Through the Hospital Door: The Role of EMTALA in Public Health Emergencies*, 31 J.L. MED & ETHICS 590, 594-595 (2003). Section 143(b)(3) of the Bioterrorism Preparedness and Response Act of 2002, Pub. L. No. 107-188, 116 Stat. 594, 627–28, suggested a narrower waiver authority, in that it allowed the Secretary to waive "sanctions" only under EMTALA's patient transfer provisions (leaving the screening requirement and private causes of action intact); *see* Special Responsibilities of Medicare Hospitals in Emergency Cases, 42 C.F.R. § 489.24(a)(2) (2005) (regulations implementing the waiver of sanctions). Finally, section 9 of the Project BioShield Act of 2004, Pub. L. No. 108-276, 118 Stat. 835, 863–64, added the authority to waive "actions" under the transfer and medical screening provisions of EMTALA. The difference between "sanctions" from the Secretary of HHS and "actions" under EMTALA is significant, in that the latter appears to also preempt private causes of action against hospitals under EMTALA's screening exam and transfer provisions.
[167] 42 U.S.C. §§ 1320b-5(b)(4), 1395nn (2005).
[168] *Id*. § 1320b-5(b)(7); Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat 1936. The waiver applies to noncompliance with the HIPAA requirements that certain healthcare entities (1) obtain a patient's agreement to speak with family members or friends;

(Continued)

Under the Food, Drug and Cosmetics Act, the Secretary of HHS can also authorize emergency use of an unapproved new drug, an unlicensed biological product, or a medical device that has not been approved or cleared for commercial distribution to be distributed and administered in the case of an emergency involving a biological, chemical, radiological, or nuclear (CBRN) agent.[169] The Secretary of HHS can authorize emergency use after:

> (A) a determination by the Secretary of Homeland Security that there is a domestic emergency or a significant potential for a domestic emergency, involving a heightened risk of attack with a [CBRN agent];
>
> (B) a determination by the Secretary of Defense that there is a military emergency, or a significant potential for a military emergency involving a heightened risk to U.S. military forces of attack with a [CBRN agent]; or
>
> (C) a determination by the Secretary [of HHS] of a public health emergency under Section 247d of Title 42 [Section 319 of the PHS Act].[170]

On January 14, 2005, HHS granted the first authorization for emergency use to the DoD for its anthrax vaccination program.[171] The DoD had requested the approval to continue anthrax vaccinations of the Armed Forces after a district court stopped the mandatory vaccination program because the FDA had failed to

(Note 168 Continued)

(2) honor a patient request to opt out of the facility directory; (3) distribute a notice of privacy practices; (4) allow patients to request privacy restrictions; and (5) allow patients to request confidential communications. 42 U.S.C. § 1320b-5(b)(7). The waiver of these requirements, along with the EMTALA requirements, are subject to a nondiscrimination provision (a hospital cannot discriminate among individuals on the basis of their ability to pay or source of payment), and are limited to 72 hours after a hospital implements a disaster protocol. *Id*. § 1320b-5(b).

[169] *See* Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(a) (2005).

[170] *Id*. § 360bbb-3(b)(1).

[171] Determination and Declaration Regarding Emergency Use of Anthrax Vaccine Absorbed for Prevention of Inhalation Anthrax, 70 Fed. Reg. 5450 (Feb. 2, 2005) (declaring an emergency justifying the use of the anthrax vaccine by DoD).

solicit additional public comments before finalizing its certification that the anthrax vaccine is a safe and effective drug.[172] The DoD filed a motion to modify the injunction based on the emergency use authorization (EUA),[173] and on April 6, 2005, the U.S. District Court for the District of Columbia granted the DoD motion and modified the injunction to allow the DoD to administer the anthrax vaccine on a voluntary basis under the emergency use authorization granted by HHS.[174]

IV. Outstanding Legal and Policy Issues in Bioterrorism Response

Despite the NRP's new framework for homeland security and public health and the broad authority of HHS to prepare for and respond to public health emergencies, there are several critical legal and policy issues that need further attention and resolution to ensure that the nation is best prepared for a response to a biological incident or other public health emergency. These issues surround the licensing system for healthcare volunteers during an emergency and liability protections for these volunteers.

A. Emergency Reciprocal Licensing System

One of the critical components of an effective response to a public health emergency involving mass casualties will be the ability to call a sufficient number of healthcare providers into service to an incident scene (or scenes). The HRSA ESAR-VHP program provides technical advice and funding to states to develop systems to pre-identify, register, and verify the credentials of healthcare providers willing to serve as volunteers

[172] *See* Doe v. Rumsfeld, 341 F. Supp. 2d 1, 16 (D.D.C. 2004) (ordering the DoD anthrax vaccination program to halt); *see also* Memorandum from Secretary of Defense Donald Rumsfeld, to the Secretaries of the Military Departments, Chairman of the Joint Chiefs of Staff, Under Secretaries of Defense, Assistant Secretaries of Defense, General Counsel of the Department of Defense, Inspector General-Department of Defense, Directors of Defense Agencies, Commandant of the U.S. Coast Guard (Oct. 27, 2004), *available at* www.anthrax.mil/media/pdf/PauseMemo.pdf (last visited May 21, 2005) (directing the military to stop the vaccination program).

[173] *See* Doe v. Rumsfeld, No. 03-707, 2005 U.S. Dist. LEXIS 1989, at *1 (D.D.C. Feb. 14, 2005).

[174] *See* Doe v. Rumsfeld, No. 03-707, 2005 U.S. Dist. LEXIS 5572, at *2-3 (D.D.C. Apr. 6, 2005). The Court left open the possibility of a future challenge to the validity of HHS's EUA grant to the DoD, and indicated that it "expressly makes no finding as to the lawfulness of any specific EUA that has been or may be approved by the Department of Health and Human Services." *Id.* at *3.

during an emergency. This system is absolutely necessary, but it is not enough.

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 directed HHS to develop the ESAR-VHP system, but specifically indicated that the Secretary of HHS did not have the authority to issue regulations regarding the provision of licenses, credentials, or hospital privileges by the states.[175] Through the ESAR-VHP program, the Secretary of HHS may "encourage" states to provide legal authority for healthcare providers licensed in another jurisdiction to provide healthcare services in their state during an emergency.[176] In addition, based on the Model State Emergency Health Powers Act,[177] seven states and the District of Columbia have adopted license reciprocity provisions.[178]

Encouragement and example are not enough in this case. The PHS Act should be amended to provide the Secretary of HHS the authority to *require* reciprocity of medical licensing during a declared public health-emergency under Section 319. Such a change could be required as a condition of states receiving emergency-preparedness grant funding or under the authority of the Commerce Clause of the U.S. Constitution. Certainly, there must be safeguards to protect the public. Building upon the ESAR-VHP system would ensure an ability to verify that a healthcare provider is licensed to practice medicine in another jurisdiction. States clearly should not loosen their licensing requirements in any way that would allow unlicensed individuals to practice medicine, but once an individual's license from another jurisdiction is verified, there should not be licensing barriers that prevent such an individual from providing needed care simply because of a geographical border. The events of

[175] 42 U.S.C. § 247d-7b (2005); *see also id.* §§ 247d-7b(a), 247d-7b(e).

[176] *Id.* § 247d-7b(d).

[177] *See* The Ctr. for Law & the Public's Health, CDC, Model State Emergency Health Powers Act (MSEHPA) (2001) [hereinafter MSEHPA], *available at* www.publichealthlaw.net/MSEHPA/MSEHPA2.pdf (last visited Apr. 21, 2005). The MSEHPA was drafted at the request of the CDC by scholars at Georgetown and Johns Hopkins Universities. *See id.*

[178] Section 608 of the MSEHPA allows the state public health authority to appoint out-of-state healthcare providers and waive all licensing requirements during a public health emergency. *Id.* § 608, at 33-34. As of July 1, 2004, seven states (Arizona, Delaware, Florida, Maryland, Missouri, South Carolina, South Dakota) and the District of Columbia had adopted some form of the licensing provision suggested by MSEHPA. *See* MSEHPA Legislative Surveillance Table 4, *available at* www.publichealthlaw.net/MSEHPA/MSEHPA%20Surveillance.pdf (last visited Apr. 10, 2005).

September and October 2001 demonstrated that public health emergencies and bioterrorist attacks do not respect geographic boundaries. Our response to such emergencies should include an ability to navigate the licensing issue.

B. Liability Protection for Healthcare Volunteers

Concerns over liability for healthcare providers and the institutions in which they work is a significant barrier to using volunteers in an emergency.

Through a variety of mechanisms, the federal government can hire healthcare providers, which provides liability protection under the Federal Tort Claims Act and, in some instances, workers' compensation protection under the Federal Employees' Compensation Act.[179]

One significant drawback to relying on federal hires to respond to a public health emergency is timing. The initial public health and medical response to a catastrophic event (or events) will be local and regional, including volunteers. The federal teams (such as those mobilizing intermittent federal hires, such as NDMS) will take twelve to twenty-four hours to arrive.

The federal government has enacted legislation to shield volunteers from liability, known as the Volunteer Protection Act (VPA).[180] The VPA provides immunity for individuals providing volunteer services to nonprofit or government organizations as long as:

> (1) the volunteer was acting within the scope of the volunteer's responsibilities in the nonprofit

[179] The NDMS enabling statute (as amended by Public Health Security and Bioterrorism Preparedness and Response Act of 2002 § 102, Pub. L. 107-188, 116 Stat. 594, 599–603) authorizes the DHS Secretary to appoint individuals to serve as intermittent employees of NDMS "in accordance with applicable civil service laws and regulations." 42 U.S.C. § 300hh-11(d)(1) (2005). Such appointment provides tort claims and workers' compensation protections. *Id.* § 300hh-11(d)(2), (e)(2). Similarly, the DHS Secretary can hire healthcare providers as Stafford Act disaster assistance employees. Section 306 of the Stafford Act provides that, in carrying out purposes of the Act, Federal agencies may appoint temporary personnel without regard to the civil service requirements of Title 5 of the U.S. Code. 42 U.S.C. § 5149(b)(1) (2005). Finally, the Secretary of HHS may hire special consultants to assist in public health service operations, without regard to the civil service requirements. 42 U.S.C. § 209(f) (2005).

[180] 42 U.S.C. §§ 14501–14505 (2005).

> organization or governmental entity at the time of the act or omission;
>
> (2) if appropriate or required, the volunteer was properly licensed, certified, or authorized by the appropriate authorities for the activities or practice in the state in which the harm occurred, where the activities were or practice was undertaken within the scope of the volunteer's responsibilities in the nonprofit organization or governmental entity; [and]
>
> (3) the harm was not caused by willful or criminal misconduct, gross negligence, reckless misconduct, or a conscious, flagrant indifference to the rights or safety of the individual harmed by the volunteer.[181]

The VPA specifically excludes liability protections for the entity or institution in which the volunteer provides services.[182] As with the licensing issue, the Model State Emergency Health Powers Act contains language that states may adopt regarding protecting volunteers from liability,[183] but a national comprehensive solution is still necessary.

The VPA should be extended to explicitly cover healthcare volunteers and the institutions in which they work during a declared public health emergency, Stafford Act emergency, or Stafford Act disaster. The VPA does not currently provide an adequate liability shield for persons providing health and medical services in national emergencies. The lack of institutional liability protection will also impede the ability of hospitals and health systems to utilize healthcare volunteers. As with the recommendation regarding licensing reciprocity, such a liability protection system necessitates an ability to verify healthcare providers' licenses and credentials. Once such a system is in place, however, providing specific liability protection for volunteer healthcare providers will provide the right incentives for providers to volunteer after a catastrophic event, which will

[181] *Id.* § 14503(a). Certain other exceptions to liability protection apply. A volunteer is not shielded from liability if her action constitutes a violent crime, a hate crime, a sexual offense, act of terrorism, a violation of civil rights laws, or where the individual was intoxicated by alcohol or any drug. *Id.* § 14503(f).

[182] *Id.* § 14503(c).

[183] *See* MSEHPA, *supra* note 177, § 804(b)(3), at 37.

translate directly into saving lives. The relevant exceptions to liability protection, currently contained in the statute (*e.g.*, willful misconduct, scope of practice, violent crimes), should be maintained for healthcare volunteers.

There is ample evidence that healthcare providers are willing to volunteer in their communities during emergencies. The Medical Reserve Corps (MRC), the medical component of the USA Freedom Corps, organizes healthcare providers in local communities to prepare for emergencies. HHS provides start-up grants for the MRC units. As of September 2004, there were over 27,500 volunteers among 212 MRC units across the country.[184] Extending the VPA to cover these and other healthcare volunteers would provide the right incentives while ensuring the public was protected against willful misconduct or other behavior that should not be shielded.

V. Conclusion

The NRP represents a significant achievement in bringing together the preparedness and response efforts of federal, state, and local jurisdictions into a single, comprehensive, all-hazards approach to domestic incident management. That is not to say it is perfect. Will the new and existing response structures work? Will the communication mechanisms and operations centers allow the response to be better coordinated? How will state and local responders and the incident command system integrate into the NRP's approach? A significant number of training opportunities, exercises, and, unfortunately, real world events will allow responders at all levels to determine what works, and the NRP review timelines will afford opportunities to change what does not.

As outlined above, HHS has significant authorities to respond to public health and medical emergencies. Additional authorities and protections, such as a national reciprocal healthcare licensing system and stronger protections for healthcare volunteers

[184] Press Release, HHS, HHS Continues to Strengthen Umbrella of Protection from Bioterrorism (Sept. 10, 2004), *available at* www.hhs.gov/news/press/2004pres/20040910.html (last visited Apr. 21, 2005).

would provide a more robust and uniform response capability during national emergencies. The DHS and other departments and agencies also have their own significant authorities that do not change under the NRP. Although there are mandates in legislation that require HHS and DHS to keep one another informed about existing and potential public health and medical situations,[185] the division of medical response assets between the departments means that it will take consistent and sustained efforts to work together to provide a unified and coordinated response. The structures outlined in the NRP ESF #8 and Biological Incident Annexes provide the framework for such a response.

[185] Section 887 of the Homeland Security Act, 6 U.S.C. § 467 (2005), states that the NRP developed by the DHS shall be consistent with section 319 of the Public Health Service Act and provides that, during the period in which the Secretary of HHS has declared a public health emergency pursuant to section 319(a) of the Public Health Service Act (42 U.S.C. 247d(a)), he shall keep relevant agencies, including the DHS, the Department of Justice (DoJ), and the FBI, fully and currently informed. In cases involving, or potentially involving, a public health emergency in which the Secretary has not made a determination under section 319(a) of the Public Health Service Act, all relevant agencies, including the DHS, the DoJ, and the FBI, are to keep the Secretary and the Director of the CDC fully and currently informed. *See id.*